

REMARKS

The present response is in response to the office action dated August 28, 2003, and further taking into consideration the telephonic interview of October 7, 2003 and the advisory action of October 31, 2003. The applicants thank the Examiner for the telephonic interview.

The present application comprises claims 1-147 of which claims 1, 113, 125 and 126 are independent claims. Claims 1, 107-109 and 113 are amended herewith. Claims 125-147 are new claims added herewith. This response refers primarily to the patentability of the independent claims. The patentability of the dependent claims follow at least for the reason of being dependent on an independent claim that is patentable. The applicants reserve the right to argue them later and respectfully request a personal interview if the Examiner feels an allowance is not forthcoming.

In the telephonic interview the language of claims 1, 107 and 113 was discussed and various possible solutions were brought forth. The advisory action did not enter the previous amendment which related to these issues.

SPECIFICATION

The Examiner states that the continuation data is not clear and also that no timely reference was made to the US application. Applicants have reviewed the continuation data and note that while a CIP relationship of an older PCT application was requested in the PCT stage, this "older" PCT application apparently never entered national phase in the US. Instead, a corresponding application 10/036,719 had been filed in the US on the same date as the PCT application and apparently including all the disclosure of the PCT case. This US application issued as U.S. Patent No. 6,127,597 issued on October 3, 2000, after the filing of the instant PCT application. Applicants have corrected the "Related Applications" section to read that the present application is related to the above PCT application and is a continuation-in-part of the US case. If this is acceptable, applicants will file an amended declaration, if required.

CLAIM REJECTIONS - 35 USC §112

The Examiner states that claims 107, 108, 113-115 are rejected under 35 USC §112 since applicants fail to disclose information referring to "surface fill factor" and "axially dense" as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art, ... to make and/or use the invention.

Referring to the term "surface fill factor", as explained in the telephonic interview and as described in the specification, for example on page 2, line 21 and on page 51, line 33, in some

spacers it is an advantage that there be a greater contact area between the spacer and the vertebra. In particular, one potential advantage of the embodiment shown in Figs. 6XA-6XC is "the ability to provide a greater surface contact area". The term "surface fill factor" was originally used in the claim to mean the ratio between the spacer geometry surface and the actual contact surface. This has now been clarified in the claim. Applicants contend, however, that the scope of the claims is unchanged. Applicants note that claim 109 was amended in a similar manner to claims 107 and 108, even though not requested by the examiner, as it used similar terminology.

Regarding claims 113-115, and the term "axially dense". As explained in the telephonic interview, the term "axially dense" in claim 113 relates to the density of extensions in the axial direction. The claim itself defines what "dense" means (e.g., as opposed to sparse). The use of axial density is clearly described on page 50 line 20 to page 51 line 3 regarding Figs. 6T-6V. As described in the text Figs. 6T-6V illustrate a spread layout of spikes on a spacer that is expanded, axially slit, flattened and viewed from above. Fig. 6V illustrates a spike distribution in which the axial spike density varies as a function of the axial location (page 50 line 33).

Applicants have amended claim 113, to clarify that the first percentage (40%) relates to how much of the body is densely covered by spikes. The second percentage (50%) defines that a section is "axially dense" if the extensions cover at least 50% of a surface of that section. Applicants respectfully submit that the scope of the claim is unchanged.

Thus, applicants respectfully submit that these changes are merely cosmetic and merely make explicit what was at least implicit in the claims as submitted.

CLAIM REJECTIONS - 35 USC §102

The Examiner states that claims 1-4, 6-8, 10, 12-16, 19-30, 46, 48, 51-55, 57, 58, 60-62, 66, 68-70, 72, 80, 92, 93, 95, 103, 106-112 and 122-124 are rejected under 35 USC §102(b) as being anticipated by Kuslich (U.S. Patent No. 5,059,193). The applicants respectfully disagree. The Examiner has not shown a *prima facie* case of anticipation since claim 1, at least, has the limitation "said plurality of slits defining at least two axially displaced extensions" (e.g. as shown in Fig. 1A by 28). In contrast Kuslich describes a plurality of ribs that all must have a same axial position in order to prevent the spacer from buckling.

The Examiner argues that the "axis" may be any axis, including a circumferential axis. Applicants respectfully note that this interpretation would still not read on Kushlich, as the claim requires the spacer to be axially compressed, while in Kushlich, a circumferential "axis" is an axis around which the spacer expands. However, in order to expedite allowance and if the Examiner

does not accept this argument, applicants suggest amending claim 1, so that the first claim element reads:

--an axial tube having a surface, a proximal end, a distal end, [and] a length and an axis defined along said length, --

Applicants further respectfully traverse the use of "axis" to describe a circumference, as it is not a reasonable interpretation of the word, especially not in the context of the claim. Thus, the Examiner has not provided "the broadest reasonable interpretation of the claims". Applicants further respectfully submit that an axial tube has "an" axis along the tube. Thus, the amendment merely makes explicit what was earlier implicit.

CLAIM REJECTIONS - 35 USC §103

The Examiner states that claims 5, 9, 11, 17, 18, 31-44, 45, 47, 49, 50, 56, 59, 63-65, 67, 71, 73-79, 81-91, 94, 96-102, 104, 105, 116, 117, 118, 119, 120, 121 are rejected under 35 USC §103(a) as being obvious over Kuslich (U.S. Patent No. 5,059,193) in view of additional art quoted by the Examiner.

The applicants respectfully disagree. The Examiner has not shown a prima facie case of obviousness since, as described above, Kuslich lacks elements of claim 1 and the Examiner has not provided art which in combination with Kuslich shows all the elements of the claims. Accordingly, the above claims, which are dependent claims, are at least patentable for the reason of being dependent on an independent claim which is patentable.

CITED ART

Applicants refer to the cited art, for example Nissenkorn (U.S. Patent No. 4,973,301) which show slotted tubes. In order to expedite issuance of this patent, applicants amended claim 1 to include a limitation of a locking element which axially locks the spacer, and plan to file a continuation with broader and/or other claims.

Applicants note that this limitation is, if anything, a broadening of a similar limitation already present in dependent claim 19.

A new claim 125 is provided with a different added limitation, as Nissenkorn is not suitable for resisting forces typical of a spine.

NEW METHOD CLAIMS

Applicants have added new method claims 126-147, to extend the scope of protection to methods described in the application as filed.

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In view of the above remarks, applicants submit that the claims are patentable over the prior art. If the Examiner does not agree regarding one or more of the claims, but is of the opinion that a telephone conversation may forward the present application toward allowance, applicants respectfully request that the Examiner call the undersigned at 1 (877) 428-5468. Please note that this is a direct *toll free* number in the US that is answered in the undersigned's Israel office. Israel is 7 hours ahead of Washington.

An allowance on the merits is respectfully requested.

Respectfully submitted,
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